

45
PUBLIC NOTICE

1985 MAR 29 PM 12:02

FEB 14 1985

ES 37
Ad
(LC)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGULATION OF A NEW CHEMICAL SUBSTANCE.

PENDING DEVELOPMENT OF INFORMATION

In the matter of:

)

Premanufacture Notice

)

Number:

)

)

)

)

P84-1042

)

)

)

)

Consent Order and Determinations Supporting Consent Order

- 1 -

TABLE OF CONTENTS

PREAMBLE

- I. Introduction
- II. EPA's Findings
 - A. Available Data
 - B. Potential Health Hazard
 - C. Potential Human Exposure
 - D. Potential Environmental Effects and Releases
 - E. Potential Risk
 - F. Information Required to Evaluate the Risk
 - G. Other Considerations
- III. EPA's Conclusions of Law
- IV. Submission of Information Under the Order
- V. Scope of the Order

CONSENT ORDER

- I. Conditional Manufacture, Import, Processing, Distribution in Commerce, Use, and Disposal Pending Submission and Evaluation of Information
- II. Terms of Manufacture, Import, Processing, Distribution in Commerce, Use, and Disposal Limitations
- III. Modification and Revocation of the Order
- IV. Effect of Consent Agreement

- 1 -

I. INTRODUCTION

Under the authority of §5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") is issuing the attached Consent Order regarding premanufacture notice ("PMN") P84-1042 submitted by [REDACTED] ("the Company"). EPA has determined that the information available to the Administrator is insufficient to permit a reasoned evaluation of potential health effects of the substance submitted for review in the PMN, and that the substance may present an unreasonable risk of injury to human health under uncontrolled conditions of manufacture, import, processing, distribution in commerce, use, and disposal.

On August 7, 1984, EPA received PMN submission P84-1042 for methylammonium n-methyldithiocarbamate ("the PMN substance") from the Company in accordance with §5(a) of TSCA (15 U.S.C. 2604(a)). The PMN substance will function as [REDACTED]. [REDACTED]. The maximum third year production volume has been estimated at [REDACTED]. EPA announced receipt of the PMN in a FEDERAL REGISTER notice on August 24, 1984 (49 FR 33718). The 90-day review period, including a voluntary suspension by the submitter, will end on February 8, 1985. The attached Consent Order will take effect on February 9, 1985.

- 7 -

The Company claimed its identity, the production volume, impurities and byproducts, use, and process data to be confidential business information. In this preamble, and in the Consent Order, all confidential business information has been enclosed in brackets.

This Order applies solely to the Company, as the manufacturer of the PMN substance. Because the Order does not prohibit manufacture, the PMN substance will be added to the TSCA Chemical Substance Inventory when production begins. Once it is on the Inventory, other persons could begin to manufacture, import, or process the PMN substance without notice to EPA and without the restrictions imposed by the Order. Therefore, the Agency may propose a Significant New Use Rule ("SNUR") under §5(a)(2) of TSCA. The SNUR would require any person who intends to manufacture, import, or process the substance under certain conditions to submit a notice for Agency review before commencement of such action. This would ensure that all importers, manufacturers, and processors are treated equally.

Under §15 of TSCA it is unlawful for any person to fail or refuse to comply with any provision of §5 or any order promulgated under §5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to §16, and specific enforcement and seizure pursuant to §17.

II. EPA's FINDINGS

A. Available Data

Test results and conclusions submitted with the PMN are summarized in Table A. EPA's general literature search identified no additional information on the toxicity of the PMN substance itself. In order to evaluate the potential chronic effects of the PMN substance, EPA has assessed data submitted with the PMN, data on analogues of the PMN substance, and data on the impurities and analogues of the impurities.

Table A
Toxicity Results/Conclusions
Submitted with the PMN Substance

<u>Test</u>	<u>Organism</u>	<u>Results/Conclusion</u>
Oral LD ₅₀	Rat	1.5 g/kg
Dermal LD ₅₀	Rabbit	1.2 g/kg
Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Moderate
Ames	Bacteria	Negative
Mouse Lymphoma (gene mutation)	Mouse lymphoma cells	Positive
Mouse Lymphoma (cytogenetic)	Mouse lymphoma cells	Positive
<u>In vitro</u> Transformation	Mouse BALB/3T3 cells	Positive

B. Potential Health Hazard

1. Absorption

Based on the test data submitted in the PMN and the physical/chemical properties of the PMN substance, the Agency has determined that the PMN substance may be absorbed by the lungs, skin, and gastrointestinal tract.

2. Potential Effects

a. Carcinogenicity/Mutagenicity

Based on submitted mutagenicity data, the PMN substance is expected to be a human mutagen. Two impurities, [REDACTED], are also expected to be mutagenic in humans based on available test data.

The Agency has determined that the PMN substance may be carcinogenic based on analogy to three structurally similar dithiocarbamates, selenium diethyldithiocarbamate, bis (2-hydroxyethyl) dithiocarbamic acid, and ethyl carbamate which have been shown to cause cancer in laboratory animals. In addition, the impurity [REDACTED] may be carcinogenic based on its structural analogy to [REDACTED] which also induced cancer in laboratory animals.

b. Developmental Toxicity

The Agency has determined that the PMN substance may cause developmental effects based on its structural similarity to sodium diethyldithiocarbamate and sodium methyldithiocarbamate. Tests have shown that these compounds produced significant effects in the estrus cycle, ejaculatory response, and litter size in mammals.

c. Neurotoxicity

Based on submitted acute test data, the Agency has determined that the PMN substance may promote acute central

nervous system depression in humans. By analogy to sodium diethyldithiocarbamate, the PMN substance could potentially inhibit dopamine beta hydroxylase which could lead to numerous nervous system effects.

C. Potential Human Exposure

During manufacturing, dermal exposure to the PMN substance may occur during sampling and transferring the material into trucks. These activities are expected to require about [REDACTED]

[REDACTED], respectively, for about [REDACTED] per year. The Agency estimates that [REDACTED]

[REDACTED] could receive a dermal dose of about 19 g/day of the PMN substance.

During use as [REDACTED], the PMN substance in solution is pumped from trucks to a holding tank and later retransferred to a reactor. Up to [REDACTED] could be dermally exposed to about 19 g/day of the PMN substance during use.

Due to the low vapor pressure of the PMN substance, inhalation exposure to a vapor is unlikely.

Based on information contained in the PMN, EPA does not expect any release of the PMN substance to drinking water that would result in exposure to the general population. Therefore, EPA did not evaluate exposure to persons drinking water containing the PMN substance.

D. Potential Environmental Effects and Releases

Based on information contained in the PMN, no releases to water are expected. Therefore, EPA has not determined that the manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may pose a significant risk of injury to the environment. This Order requires that the PMN substance be disposed of in accordance with the PMN.

E. Potential Risk

Based on the above analysis, unprotected workers exposed to the PMN substance during manufacture and use may experience a significant risk of carcinogenic, developmental, and neurotoxic effects. However, the Agency finds that the use of appropriate protective equipment will significantly reduce exposure and potential risk.

F. Information Required to Evaluate the Risk

A reasoned evaluation of the risk resulting from exposure to the PMN substance would be possible if the Agency were provided with data on the potential carcinogenic, developmental, and neurotoxic effects of the PMN substance. Such data could be developed in a two-year rodent bioassay, a two-generation reproductive assay, a two-species teratology study, repeated exposure and neuropathy testing with correlative functional observation, and acute exposure neurotoxicity testing. The

Agency may also consider alternative means of addressing the potential risk.

G. Other Considerations

The direct costs associated with this Order may be broken down into three parts: 1) protective equipment; 2) recordkeeping costs, and 3) labeling costs.

The Company indicated that it intends to control exposure of the PMN substance through the use of impervious gloves, chemical safety goggles, and protective clothing. Therefore, the cost of this equipment does not represent additional cost attributable to this Order.

The Order also requires that the Company maintain certain records. The present value of costs associated with recordkeeping requirements over a ten-year period (assuming a 10 percent discount rate) is \$1525; annualized cost is \$225.

Labels must accompany the PMN substance when distributed off-site. The initial cost of the labeling requirements will be between \$135 and \$500, which represents the development cost of the label. The annualized cost of labeling is \$75. A Material Safety Data Sheet ("MSDS") is estimated to cost \$20.

If the Company were to develop the data required to provide a reasoned evaluation of the risk by conducting the tests described in paragraph F, the Agency estimates the costs of these tests to be between \$956,000 and \$1,209,000. The cost of testing is

viewed as prohibitive. By issuing this Order, which allows manufacture, import, processing, distribution in commerce, use, and disposal under specified conditions, EPA has adopted the least burdensome regulatory approach, while protecting public health.

In light of the above analysis, there is no basis for concluding that the requirements of the Consent Order would impose an undue economic burden on the Company. Therefore, EPA finds that issuance of the Order will not result in any significant loss of benefits to society.

III. EPA's CONCLUSIONS OF LAW

The following findings constitute the bases of the Consent Order:

A. EPA is unable to determine the potential for carcinogenic, developmental, and neurotoxic effects from exposure to the PMN substance. EPA therefore concludes, pursuant to §5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the health effects of the PMN substance.

B. In light of the potential risk of carcinogenic, developmental, and neurotoxic effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, and the Agency's conclusion that the issuance of this Order will not result in any significant loss of benefits to society, EPA has concluded,

pursuant to §5(e)(1)(A)(ii) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to health.

IV. SUBMISSION OF INFORMATION UNDER THE ORDER

The Order does not require the Company to develop test data or other information at this time. Rather, it places certain restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance for any non-exempt commercial purpose until such time as sufficient test data or other information are provided to, and evaluated by, EPA. Submission of information to EPA may result in either modification or revocation of the Order, or in continuation of the restrictions pending rulemaking proceedings under §6(a) of TSCA. EPA will complete its evaluation of such data within a reasonable period of time after they are submitted.

Any test data submitted must include protocols, raw data, and results. The data must be developed according to TSCA Good Laboratory Practices Regulations at 40 CFR Part 792 (48 FR 53922, November 29, 1983), and through the use of methodologies generally accepted at the time these studies are initiated. Failure to do so may lead the Agency to find such data to be insufficient to reasonably evaluate the health effects of the substance. If the Company elects to perform testing, EPA encourages consultation with the Agency before selecting protocols or developing the information.


V. SCOPE OF THE ORDER

The Consent Order prohibits manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance for "any non-exempt commercial purpose" except in accordance with detailed restrictions in the Order. Exempt commercial purposes include two activities: (1) manufacture, import, processing, distribution in commerce, and use in small quantities solely for research and development at any time if the activities meet the definition in 40 CFR 720.3(cc) and comply with section 5(h)(3) of TSCA; and (2) manufacture of the PMN substance solely for export if the activities meet the definition in 40 CFR 720.3(s) and, when distributing the PMN substance in commerce, the Company labels the substance in accordance with section 12(a)(1)(B) of TSCA and provides notice of export in accordance with section 12(b)(2) of TSCA and 40 CFR Part 707. Until the Company begins manufacture for use in the United States, other than small quantities solely for research and development, it is free to manufacture the PMN substance solely for export without complying with the restrictions in the Consent Order. However, once the Company begins to manufacture any quantity of the PMN substance for use in the United States, other than for research and development, no further activity would qualify as "solely for export," even if some amount of the PMN substance is later exported. Exempt commercial purposes also includes the activities described in 40 CFR 720.30(g) and (h).

CONSENT ORDER

Under the authority of §5(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. 2604(e), the Environmental Protection Agency ("EPA" or "the Agency") issues the following Order to take effect on February 9, 1985.

I. CONDITIONAL MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION
IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND
EVALUATION OF INFORMATION

 ("the Company") is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substance methylammonium n-methyldithiocarbamate ("the PMN substance") for any non-exempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the health effects of the substance, and the completion of EPA's review of that information, in any manner inconsistent with the provisions of Part II of this Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION
IN COMMERCE, USE, AND DISPOSAL LIMITATIONS

The PMN substance shall not be manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States for any non-exempt commercial purpose except under the following conditions:

A. The Company shall not cause any other person to manufacture

or import the PMN substance.

B. The Company shall use the PMN substance only as [REDACTED]
[REDACTED]

C. The Company shall not distribute the PMN substance in commerce, except for disposal, other than to another site controlled by the Company.

D. The Company shall dispose of the PMN substance as described in Premanufacture Notice P84-1042.

E. During manufacture, processing, or use of the PMN substance at any site controlled by the Company, or during response to emergencies or spills involving the PMN substance at any site controlled by the Company, any person under the control of the Company, including employees and contractors, who may be dermally exposed to the PMN substance shall wear:

1. Gloves determined by the Company to be impervious to the PMN substance under the conditions of exposure, including the duration of exposure. The Company shall make this determination either by testing the gloves under the conditions of exposure or by evaluating the specifications provided by the manufacturer of the gloves. Testing or evaluation of specifications shall include consideration of permeability, penetration, and potential chemical and mechanical degradation by the PMN substance and associated chemical substances;

2. Chemical safety goggles or equivalent eye protection;
and

3. Clothing which covers any other exposed areas of the
arms, legs, and torso.

F. The Company shall inform all persons described in paragraph E
of the requirements of this Order in writing, or by presenting
the information as part of a training program in safety meetings
at which attendance is recorded, by means of the following
statements:

WARNING: Avoid contact. Contact with skin may be
harmful. Chemicals similar in structure to [Insert
appropriate name] have been found to cause cancer
and reproductive effects in laboratory animals.
[Insert appropriate name] may produce effects on
the nervous system. To protect yourself, you must
wear safety goggles or equivalent eye protection,
impervious gloves, and protective clothing while
handling this material.

G. The Company shall affix to each container of the PMN
substance, or of a formulation containing the PMN substance,
which is intended for distribution to another site controlled by
the Company, a label which includes a Warning Statement. The
Warning Statement shall consist only of the language in paragraph
F. The first word on the label shall be capitalized, and the

type size for the first word shall be no smaller than six point type for a label five square inches or less in area, ten point type for a label above five but below ten square inches in area, twelve point type for a label above ten but below fifteen square inches in area, fourteen point type for a label above fifteen but below thirty square inches in area, or eighteen point type for a label over thirty square inches in area. The type size of the remainder of the Warning Statement shall be no smaller than six point type. All required label text shall be of sufficient prominence, and shall be placed with such conspicuousness relative to other label text and graphic material, to insure that the Warning Statement is read and understood by the ordinary individual under customary conditions of purchase and use.

H. The Company shall maintain the following records until five years after the dates they are created, and shall make them available for inspection and copying by EPA in accordance with §11 of TSCA:

1. Any determination that gloves are impervious to the PMN substance as required by paragraph E.1.
2. Names used for the PMN substance and the accompanying periods these names are used.
3. Names of persons who have been informed in accordance with paragraph F, the means by which they were informed, and the

dates they were informed.

4. Dates of shipments of containers which have been labeled in accordance with paragraph G, and the identities of the sites to which they have been shipped.

5. Information on disposal of the PMN substance, including: dates waste material is disposed of, location of disposal sites, volume of any disposal material, and method of disposal.

III. MODIFICATION AND REVOCATION OF THE ORDER

The Company may petition EPA at any time to modify or revoke this Order. EPA will issue a modification or revocation if it determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment.

IV. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to the Order pursuant to §5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to §5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

Date 2/8/85

John A. Moore
John A. Moore
Assistant Administrator
for Pesticides and Toxic
Substances

Date _____

[REDACTED]